

# Report From the Pediatric Mild Traumatic Brain Injury Guideline Workgroup:

Systematic Review and Draft Clinical Recommendations for Healthcare Providers on the  
Diagnosis and Management of Mild Traumatic Brain Injury Among Children



National Center for Injury Prevention and Control,  
Board of Scientific Counselors Meeting  
September 7, 2016

# Public Health Burden

- Between 2005 and 2009, the number of pediatric patients seen for mild traumatic brain injury (mTBI) included:
  - More than 2 million outpatient visits
  - Almost 3 million emergency department (ED) visits
- Children are at increased risk for mTBI
- While most have a good recovery, some children experience both acute and long-term problems affecting their:
  - Physical
  - Cognitive, and/or
  - Psychological functioning



# Information and Resource Gaps



- No current evidence-based clinical guidelines exist on best practices for the diagnosis and management of pediatric mTBI in the United States
- Clinical guidance for healthcare providers on pediatric mTBI is critical to improving the health and safety of this vulnerable population

# Pediatric mTBI Guideline Workgroup

**Goal:** Improve diagnosis and management of mTBI among children ages 18 years and younger by:

- Conducting a rigorous systematic review of the scientific literature
- Creating evidence-based clinical recommendations for healthcare providers in both acute and primary care settings





# Pediatric mTBI Guideline Workgroup

- 21 Workgroup members
- 21 Ad-Hoc experts
- 6 federal representatives



# Selection of Experts

- Workgroup members were selected based on their:
  - Demonstrated experience with TBI and pediatrics
  - Credentials and expertise in a wide range of specialties
- Workgroup members represent a wide range of specialties and professional settings:
  - Clinical
  - Research
  - Healthcare systems
  - Sports and school environments
- Ad-Hoc experts were:
  - Invited to participate in a consulting capacity
  - Identified using the same process and selection criteria as Workgroup members

# Disclosure of Relationships

- Workgroup members and Ad-Hoc experts were required to disclose financial and intellectual conflicts of interest
- Conflict of interest forms were collected in 2012 and 2016
- All Workgroup members and Ad-Hoc experts also completed a standardized form, which required:
  - Disclosure of potential non-financial competing interests
  - Financial interests
  - Engagement in clinical practice overlapping with proposed clinical recommendations for clinicians
  - Ongoing research support

# Disclosure of Relationships (continued)

- The Workgroup members and Ad-Hoc experts disclosed that they have no conflicts of interest
- Disclosure statements from experts about activities related to the content of the report are detailed in the Disclosure of Relationships section in the final Workgroup report





# WORKGROUP REPORT

DRAFT



# Snapshot: Workgroup Report

The Workgroup Report is the:

- Most comprehensive review of pediatric mTBI scientific evidence to date—**summarizing 25 years of scientific research**
- First U.S. evidence-based clinical recommendations for healthcare providers that:
  - Cover all causes of pediatric mTBI
  - Include guidance for:
    - Primary care
    - Outpatient specialty
    - Inpatient care
    - Emergency care settings

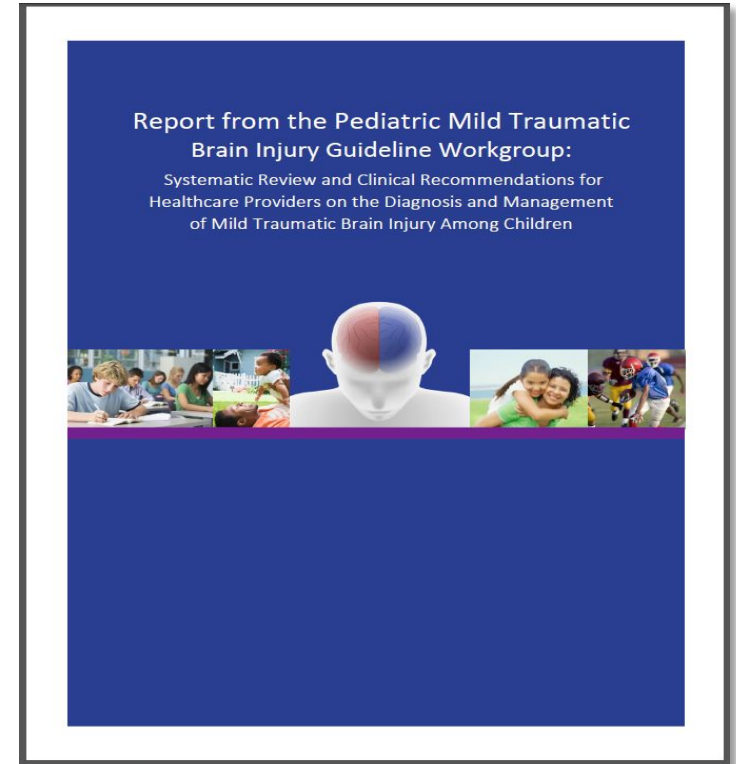
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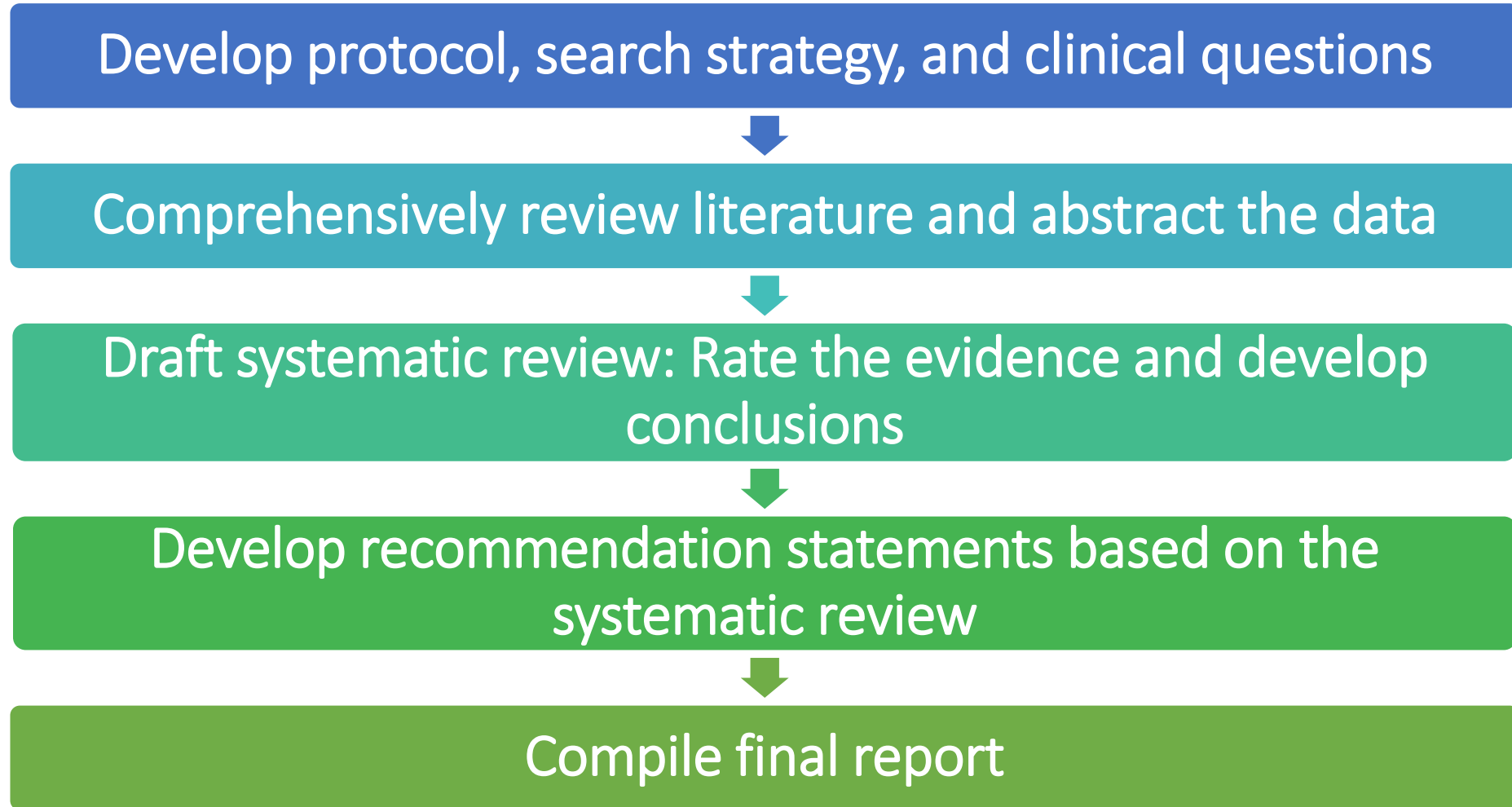
# Workgroup Report

## Report contents:

- Executive Summary
- Overview of the Process:
  - Selection of the Clinical Questions
  - Literature Search Strategy
- Systematic Review
- Draft Clinical Recommendations for Healthcare Providers
- Appendices:
  - Rosters for Both Workgroup Members and Ad-Hoc Experts
  - Rationale for Clinical Questions
  - Literature Search Strategy
  - PRISMA Diagram
  - Classification of Evidence Scheme
  - Evidence Tables
  - Methodology of the Recommendation Process
  - Clinical Contextual Profiles



# Overview of the Process



# Methodology

- Systematic review and draft clinical recommendations for healthcare providers were developed using methods of the American Academy of Neurology
- Process is compliant with the 2010 standards of the Institute of Medicine (National Academy of Sciences)



# Defining mTBI

- mTBI is one of the most common neurological disorders; however, there is no universally accepted definition
- For the purposes of *this* report, a wide clinical and functional definition was used in order to be cognizant of the heterogeneity of presentations and outcomes of this injury
- Evidence analyzed included children with mTBI or concussion as described in the literature:
  - Based on historical definitions
  - Encompassing Glasgow Coma Scale (GCS) scores of 13-15
  - With and without the complication of intracranial injury on neuroimaging
  - Regardless of potentially requiring a hospital admission and/or neurosurgical intervention



# Selection of Clinical Questions



- Independently nominated pertinent clinical questions using the Patient-Intervention-Comparator or Co-Intervention-Outcome (PICO) format
- PICO questions must have four components:
  1. Population
  2. Intervention
  3. Co-Intervention
  4. Outcome
- Each question was evaluated using a 9-point ordinal scale of importance using a modified Delphi process
- After three rounds of voting, six clinical questions were selected

# Six Clinical Questions

1. For children with suspected mTBI, do specific tools, as compared with a reference standard, accurately diagnose mTBI?
2. For children presenting to the ED (or other acute care setting) with mTBI, how often does routine head imaging identify important intracranial injury?
3. For children presenting to the ED (or other acute care setting) with mTBI, which features identify patients at risk for important intracranial injury?
4. For children with mTBI, what factors identify patients at increased risk for ongoing impairment, more severe symptoms, or delayed recovery (< 1 year post-injury)?
5. For children with mTBI, which factors identify patients at increased risk of long-term ( $\geq 1$  year) sequelae?
6. For children with mTBI (with ongoing symptoms), which treatments improve mTBI-related outcomes?





# LITERATURE REVIEW and DATA ABSTRACTION

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# Literature Search Strategy

- Initial search: January 1, 1990 – November 30, 2012
- Updated search: December 1, 2012 – July 31, 2015
- Databases searched: MEDLINE (via PubMed), EMBASE, ERIC, SPORTDISCUS, and CINAHL



# Literature Review and Data Abstraction

- Abstracts and full-text articles were reviewed by two independent experts
- Agreement was required at each step of abstract review and full-text review processes
- Data from each selected article was extracted:
  - By at least two experts working independently
  - Using a standardized form
- Disagreement regarding the extracted elements, classification of evidence, or assessment of effect size was resolved through consensus among Workgroup members





# DATA ANALYSIS and SYSTEMATIC REVIEW

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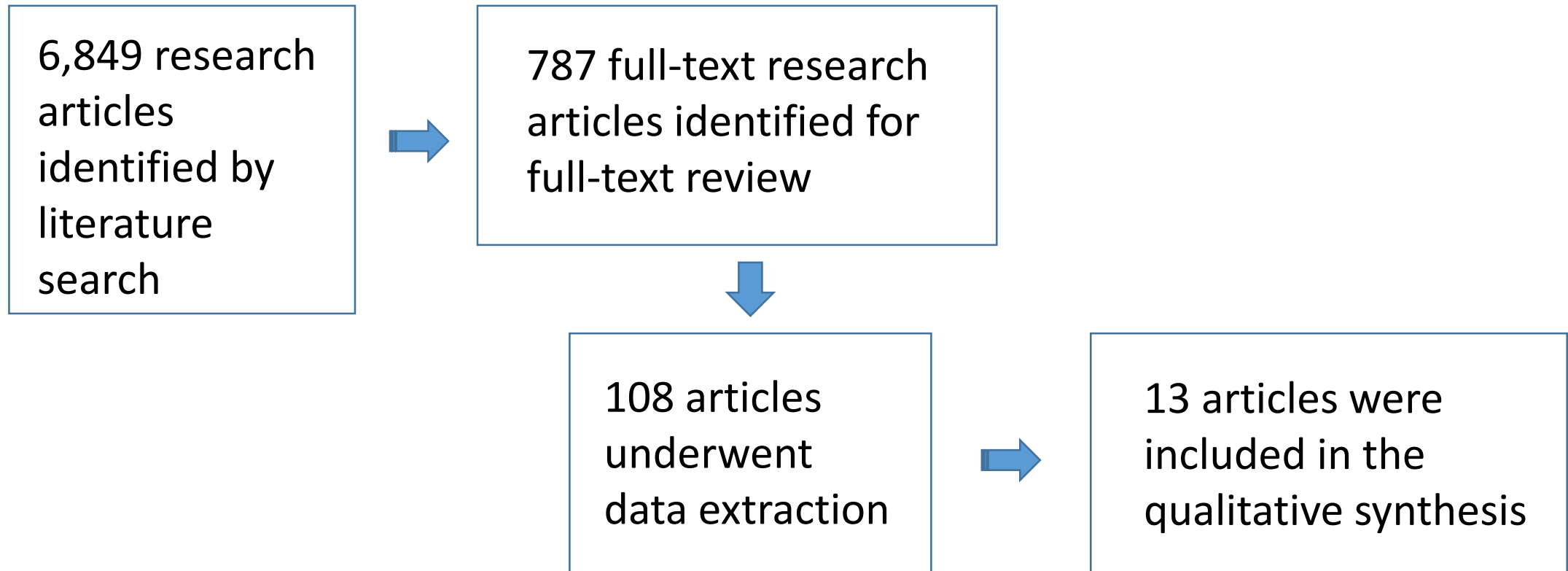


# Snapshot: Systematic Review

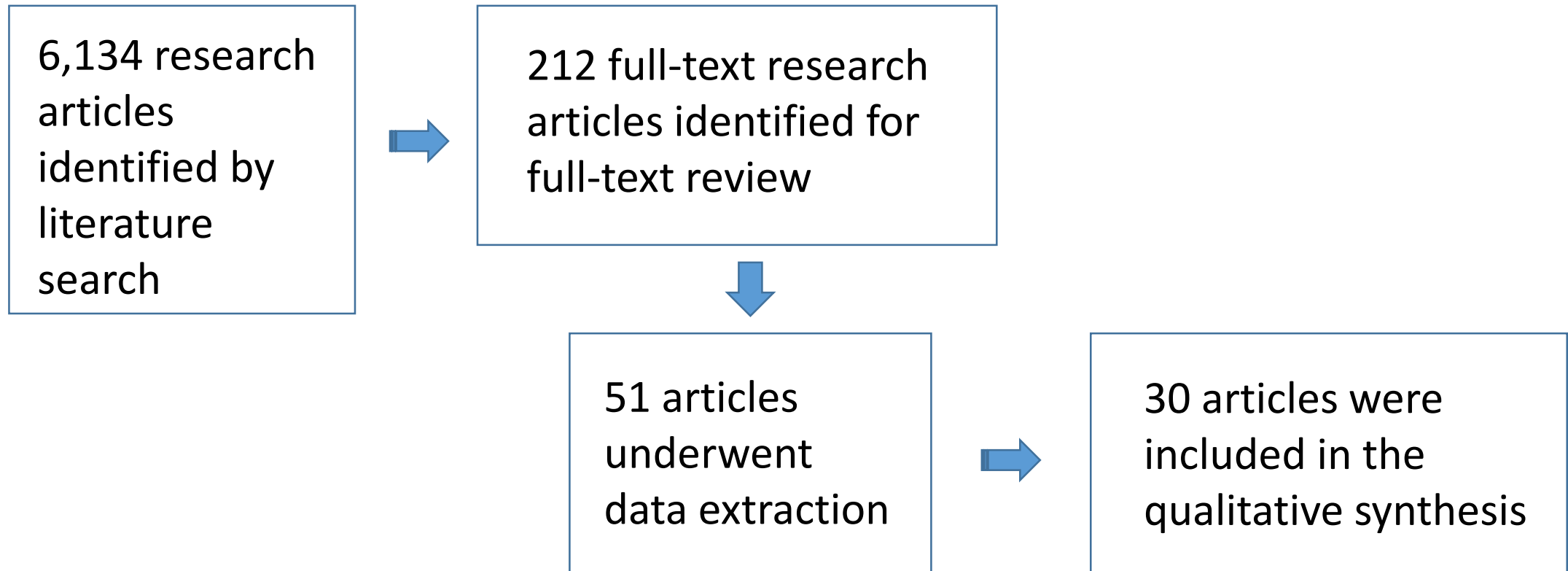
Across all six clinical questions:

- **More than 37,000** abstracts reviewed
- **Almost 2,900** full-text articles reviewed
- **More than 340** articles underwent data extraction
- **Almost 100 articles** included in the qualitative synthesis

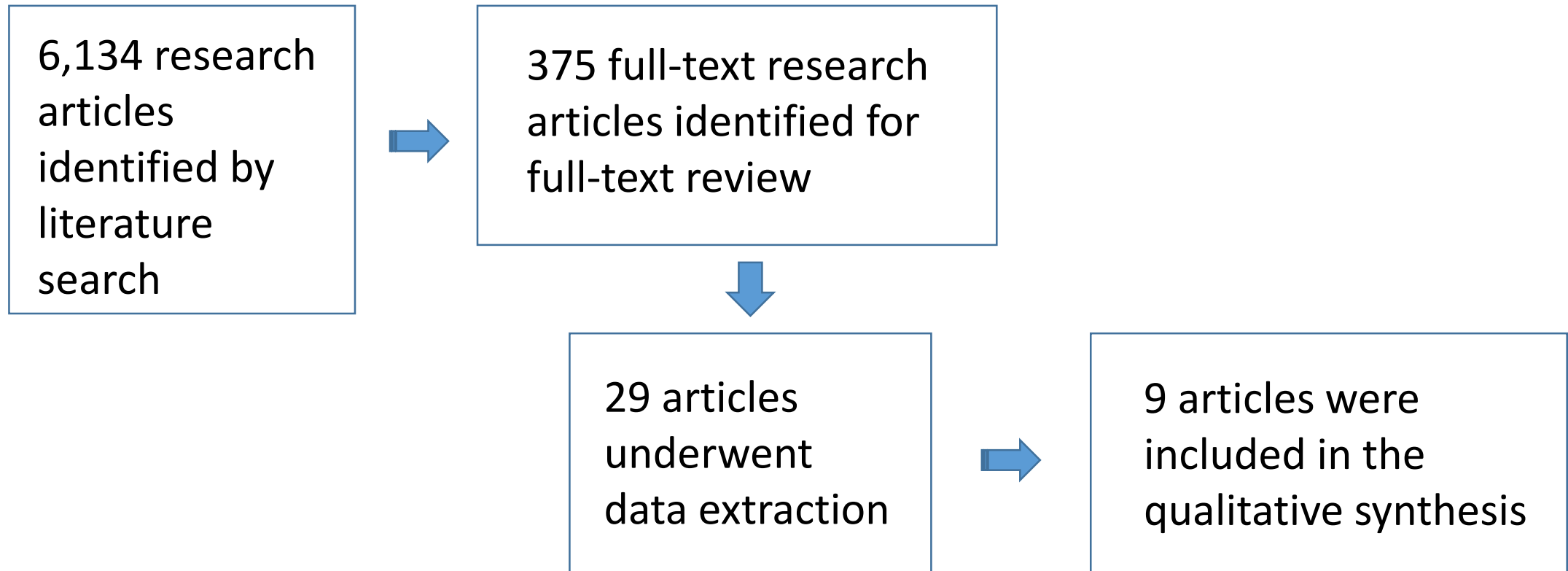
# Question 1 Article Flow



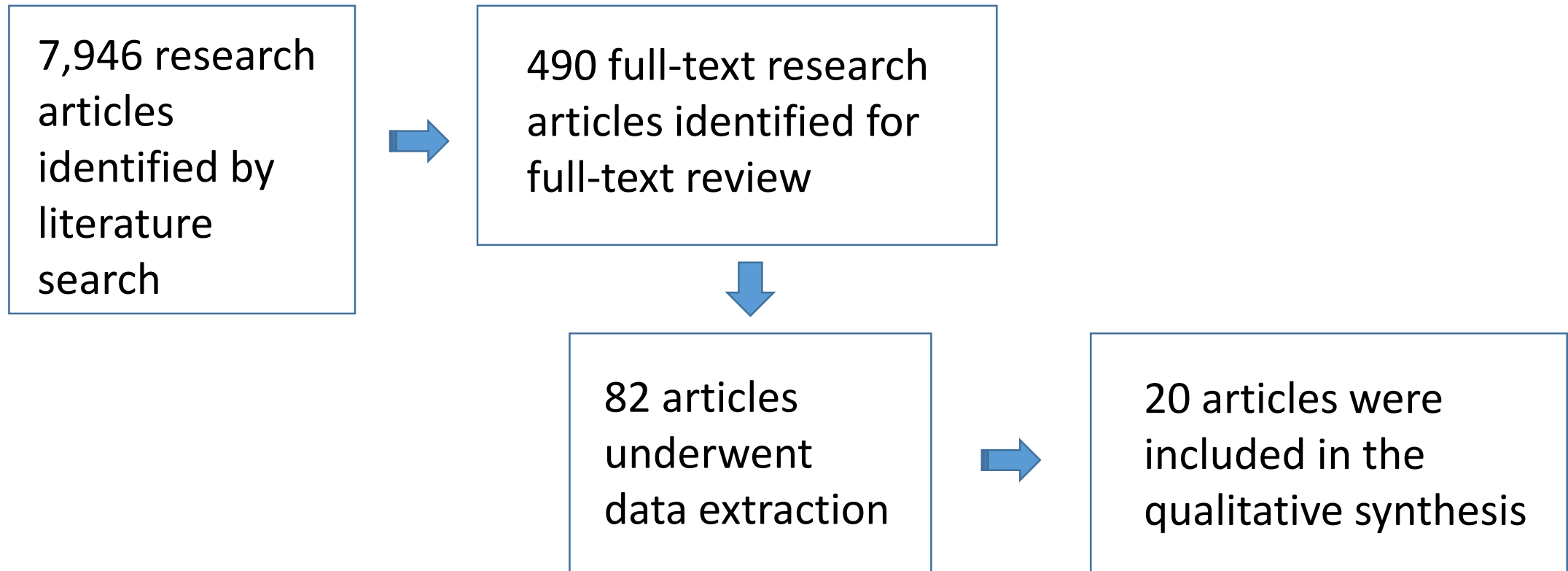
# Question 2 Article Flow



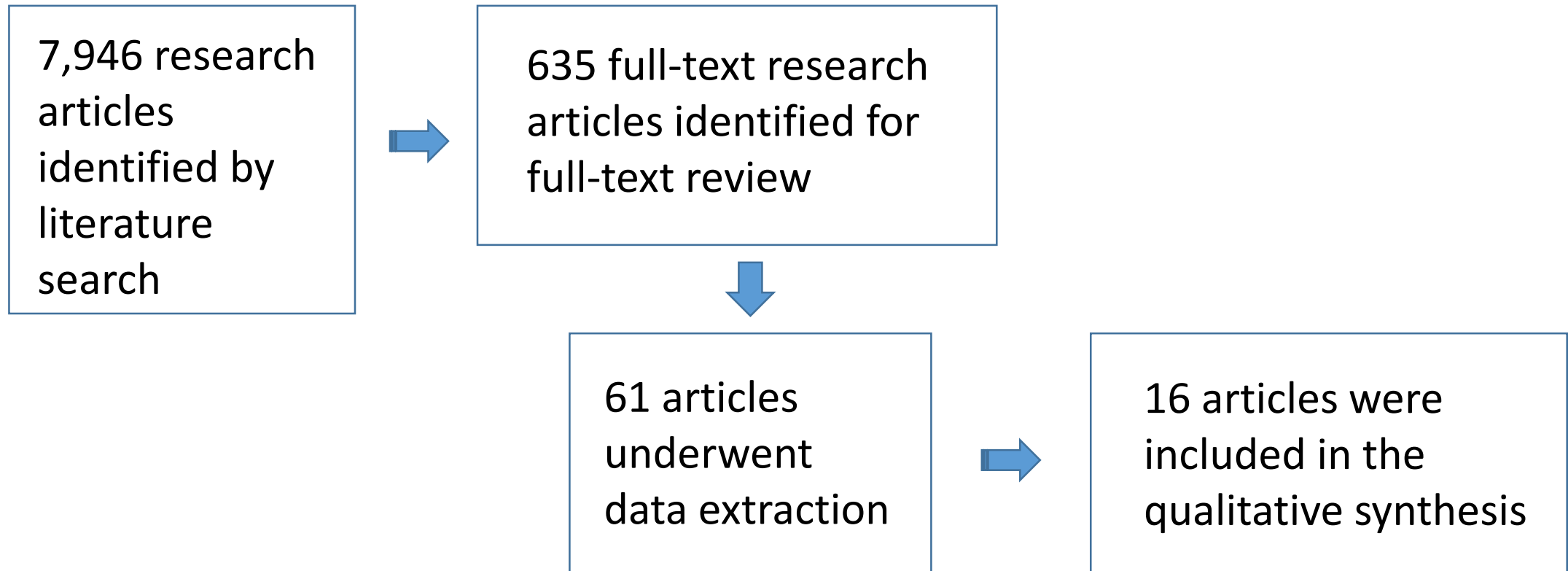
# Question 3 Article Flow



# Question 4 Article Flow

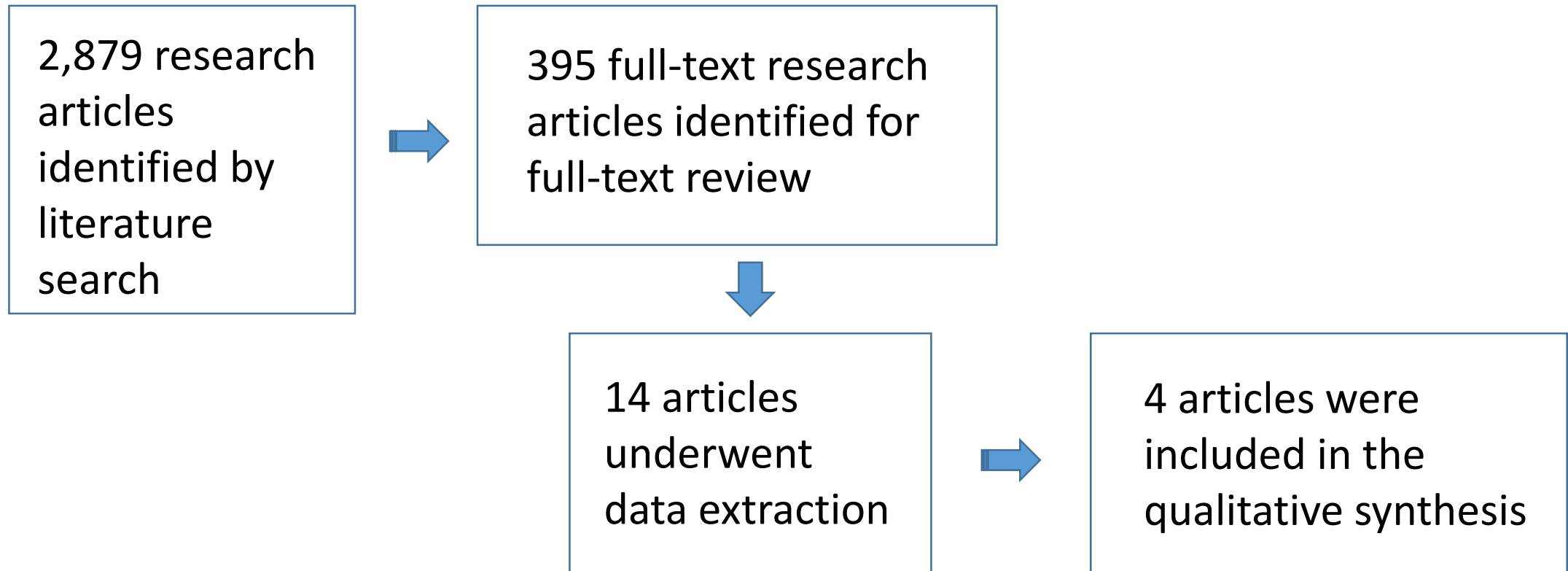


# Question 5 Article Flow





# Question 6 Article Flow



# Rating the Evidence

- Findings from the literature review and data abstraction were compiled into evidence tables
- To judge overall confidence in the evidence, the Workgroup used a modified GRADE process. This process explicitly considered:
  - Risk of bias in individual studies (class of evidence)
  - Consistency between studies
  - Precision, directness, and magnitude of effect relative to the risk of bias
  - Presence of an expected dose-response relationship
  - Direction of bias



# Rating the Evidence (continued)

- The risk of bias in each study was determined using the classification of evidence scheme for:
  - Screening
  - Diagnostic
  - Prognostic
  - Therapeutic questions
- All articles were reviewed and abstracted by a minimum of two independent experts at each phase, requiring consensus for inclusion
- Evidence tables were constructed from abstracted study characteristics

# Development of Conclusions



- Conclusions were derived from the synthesized evidence for each clinical question
- Each conclusion evaluated four types of information:
  1. Class of evidence
  2. Measure of association
  3. Measure of statistical precision
  4. Consistency between studies

# Systematic Review: Key Findings

1. For children with suspected mTBI, do specific tools, as compared with a reference standard, accurately diagnose mTBI?

## **BLOOD/SERUM TESTING: S100B**

**Conclusions:** There is insufficient evidence to determine whether serum S100B is a useful diagnostic indicator in distinguishing children with and without mTBI.

**Confidence Level: Very Low**

## **COMPUTERIZED COGNITIVE TESTING AND SYMPTOM SCALES**

**Conclusions:** The combination of computerized cognitive testing and Post-Concussion Symptom Scale likely distinguish children with and without mTBI.

**Confidence Level: Moderate**

# Systematic Review: Key Findings

2. For children presenting to the ED (or other acute care setting) with mTBI, how often does routine head imaging identify important intracranial injury?

## CT/INTRACRANIAL INJURY FINDINGS

**Conclusions:** Routine head CT on children in the acute care setting possibly identifies intracranial injury in 7.5% (95% CI, 6.0%-9.1%) of patients.

**Confidence Level: Low**

## CT/CLINICALLY IMPORTANT OUTCOME

**Conclusions:** Routine head CT performed on children presenting to an acute care setting with mTBI possibly identifies injuries with clinically important outcomes in 1.9% (95% CI, 1.3%-2.5%) of patients.

**Confidence Level: Low**





# Systematic Review: Key Findings

3. For children presenting to the ED (or other acute care setting) with mTBI, which features identify patients at risk for important intracranial injury?



## YOUNGER AGE (LESS THAN 2 YEARS OF AGE)

**Conclusions:** Age < 2 years at the time of the mTBI is likely associated with a small increased risk of ICI but is not likely associated with an increased risk of ICI requiring neurosurgical intervention.

**Confidence Level: Moderate**

# Systematic Review: Key Findings

3. For children presenting to the ED (or other acute care setting) with mTBI, which features identify patients at risk for important intracranial injury?

## GLASGOW COMA SCALE SCORE AT PRESENTATION

**Conclusions:** Children presenting with a GCS < 15 following mTBI are highly likely to be at a moderate increased risk for intracranial injuries (RD 7.5%, 95% CI, 6.2%-8.8%).

## CLINICAL DECISION RULES

**Confidence Level: High**

**Conclusions:** Validated prediction rules are highly likely to be useful in identifying children at low risk for ICI.

**Confidence Level: High**

# Systematic Review: Key Findings

4. For children with mTBI, what factors identify patients at increased risk for ongoing impairment, more severe symptoms, or delayed recovery (< 1 year post-injury)?

## **PREMORBID FACTORS—NEUROLOGICAL/PSYCHIATRIC PROBLEMS**

**Conclusions:** Premorbid factors such as neurological/psychiatric problems, learning difficulties, behavioral problems, and postconcussion-like symptoms are highly likely to be associated with an increased risk of persistent symptoms and behavioral problems 3-6 months post-injury in children with mTBI who present to an ED and likely associated with an increased risk in children with mTBI in general.

**Confidence Level: High for children with mTBI presenting to an ED;  
Moderate for children with mTBI in general**

# Systematic Review: Key Findings

4. For children with mTBI, what factors identify patients at increased risk for ongoing impairment, more severe symptoms, or delayed recovery (< 1 year post-injury)?

## **PREMORBID FACTORS—PRIOR HISTORY OF mTBI**

**Conclusions:** History of prior concussion is likely associated with a longer period until symptom resolution and higher rates of medical retirement in high school athletes after concussion and may be more likely when the injury is sustained while playing football. Additional evidence is needed to determine whether repeat concussion is associated with prolonged resolution of symptoms or higher rates of medical disqualification in mTBI in general.

**Confidence Level: Moderate for the association between recurrent concussion and outcome in high school athletes; low for the association between recurrent concussion and outcome for mTBI in general**

# Systematic Review: Key Findings

5. For children with mTBI, which factors identify patients at increased risk of long-term ( $\geq 1$  year) sequelae?

## INTRACRANIAL LESION AND POSTCONCUSSIVE SYMPTOMS

**Conclusions:** The presence of an intracranial lesion on MRI may be associated with an increased risk of increased cognitive symptoms after mTBI at 12 months post-injury, when it occurs in children of lower cognitive ability.

**Confidence Level: Moderate**

## PRE-INJURY FAMILY FUNCTIONING AND PSYCHIATRIC OUTCOME

**Conclusions:** Poor pre-injury family functioning likely places children at elevated risk for novel psychiatric disorder 6-12 months after mTBI.

**Confidence Level: Moderate**

# Systematic Review: Key Findings

6. For children with mTBI (with ongoing symptoms), which treatments improve mTBI-related outcomes?

## AMANTADINE

**Conclusions:** In children with mTBI with ongoing symptoms, there is insufficient evidence to determine the therapeutic efficacy of amantadine.

**Confidence Level: Very Low**

## STRICT REST/POSTCONCUSSIVE SYMPTOM SCORE (SYMPTOM ASSESSMENT)

**Conclusions:** There is insufficient evidence to support or refute an effect of strict rest on symptoms in children with mTBI.

**Confidence Level: Very Low**





# **DRAFT CLINICAL RECOMMENDATIONS for HEALTHCARE PROVIDERS**

DRAFT





# Snapshot: Draft Clinical Recommendations for Healthcare Providers

46 evidence-based clinical recommendations for healthcare providers that cover:

- **Diagnosis:** 11 recommendations
- **Prognosis:** 12 recommendations
- **Management and Treatment:** 23 recommendations

# Development Process:

## Draft Clinical Recommendations for Healthcare Providers

- Developed based on the evidence established by the:
  - Systematic review
  - Related evidence
  - Scientific principles
  - Expert consensus inference
- Four rounds of voting to determine consensus using a modified Delphi process
  - To be accepted/reach consensus, 80% of the group were required to be in consensus

# Assigning Levels of Obligation

- Draft recommendation levels were assigned based on voting:
  - **Level A:** (Must do) Almost all patients in almost all circumstances would want the recommendation followed
  - **Level B:** (Should do) Most patients in most circumstances would want the recommendation followed
  - **Level C:** (May do) Some patients in some circumstances would want the recommendation followed
  - **Level U:** No recommendation can be made
  - **Level R:** Do only in a research setting

# Guidance on Diagnosis

## **Diagnosing mTBI Following Head Injury in Children (as compared to absence of brain injury or more severe injuries)**

- **Risk Factor Identification and Imaging**
  - Risk Factors and Computed Tomography (CT)
  - Brain Magnetic Resonance Imaging (MRI)
  - Single Photon Emission Computed Tomography (SPECT)
  - Skull X-ray
- **Neuropsychological Tools**
  - Symptom Scales
  - Computerized Cognitive Testing
  - Standardized Assessment of Concussion
- **Serum Biomarkers**

# Guidance on Prognosis

## Prognosis of mTBI in Children

- General Healthcare Provider Counseling of Prognosis
- Prognosis Related to Premorbid Conditions
- Assessment of Cumulative Risk Factors and Prognosis
- Assessment Tools and Prognosis
- Interventions for mTBI With Poor Prognosis



# Guidance on Management and Treatment

## Management and Treatment of Children with mTBI

- **General Areas of Treatment for Patients and Families**
  - Patient/Family Education and Reassurance
  - Cognitive/Physical Rest and Aerobic Therapy
  - Psychosocial/Emotional Support
  - Return to School
- **Symptom/Problem-Specific Treatment/Management**
  - Post-Traumatic Headache Management
  - Vestibulo-Oculomotor
  - Sleep
  - Cognitive Impairment





EXAMPLES of DRAFT CLINICAL RECOMMENDATIONS for  
HEALTHCARE PROVIDERS INCLUDED in the REPORT



# Example: Draft Recommendations on Diagnosis

Healthcare providers *should* use validated clinical decision rules to identify children at low risk for intracranial injury, in whom head CT is not indicated, as well as children who may be at higher risk for clinically important ICI, and therefore may warrant head CT. Existing decision rules combine a variety of risk factors, including the following:

- Age < 2 years old
- Vomiting
- Loss of consciousness
- Severe mechanism of injury
- Severe or worsening headache
- Amnesia
- Nonfrontal scalp hematoma
- Glasgow Coma Score < 15
- Clinical suspicion for skull fracture

**Level of Obligation: B**

# Example: Draft Recommendations on Diagnosis (continued)

Healthcare providers *should* use an age-appropriate, validated symptom rating scale as a component of the diagnostic evaluation in children presenting with acute mTBI.

**Level of Obligation: B**

# Example: Draft Recommendations on Prognosis

Healthcare providers *should* counsel patients and families that the large majority (70%-80%) of children with mTBI do not show significant difficulties that last more than 1–3 months post injury.

**Level of Obligation: B**

Healthcare providers *should* counsel patients and families that although some factors predict an increased or decreased risk for prolonged symptoms, each child's recovery from mTBI is unique and will follow its own trajectory.

**Level of Obligation: B**



# Example: Draft Recommendations on Prognosis (continued)

Healthcare providers *should* counsel children and families completing pre-participation athletic examinations and children with mTBI as well as their families that recovery from mTBI might be delayed in those with:

- Premorbid histories of mTBI
- Lower cognitive ability (for children with an intracranial lesion)
- Neurological or psychiatric disorder
- Learning difficulties
- Increased pre-injury symptoms (i.e., similar to those commonly referred to as “postconcussive”)
- Family and social stressors

**Level of Obligation: B**

# Example: Draft Recommendations on Prognosis (continued)

Healthcare providers *should* use a combination of tools to assess recovery in children with mTBI.

**Level of Obligation: B**

# Example: Draft Recommendations on Treatment and Management

In providing education and reassurance to the family, the healthcare provider *should* include the following information:

- Warning signs of more serious injury
- Description of injury and expected course of symptoms and recovery
- Instructions on how to monitor postconcussive symptoms
- Prevention of further injury
- Management of cognitive and physical activity/rest
- Instructions regarding return to play/recreation and school
- Clear clinician follow-up instructions

**Level of Obligation: B**

# Example: Draft Recommendations on Treatment and Management (continued)

To assist children returning to school following mTBI, medical and school-based teams *should* counsel the student and family regarding the process of gradually increasing the duration and intensity of academic activities as tolerated, with the goal of increasing participation without significantly exacerbating symptoms.

**Level of Obligation: B**



# RESEARCH GAPS



# Research Gaps: Examples



- Evaluate the incidence and clinical meaningfulness of findings on MRI, including “ultra-fast” MRI studies
- Refine clinical decision rules for cranial imaging in specific subpopulations of children with mTBI
- Assess the effect of age at injury and gender on early symptoms or impairment after mTBI among children and youth



# Research Gaps: Examples (continued)

- Understand the relative effects of premorbid factors compared to injury factors on the risk for more severe symptoms or delayed recovery
- Examine the risks for long-term negative outcomes following mTBI in children, especially over intervals extending beyond 1 year post-injury
- Assess long-term outcome in studies extending into adulthood to better examine the likelihood of negative outcomes during adulthood and the risk factors that predict them
- Use randomized controlled trials to contribute to interpretable evidence for the best practices in treatment of children with mTBI, including interventions in acute and chronic settings



# EXPERTS and ACKNOWLEDGMENTS

# Workgroup Members

Chair: Shelly D. Timmons, MD, PhD, FACS, FAANS

- Edward C. Benzel, MD
- Catherine Broomand, PhD, ABPP-CN
- Linda Ewing-Cobbs, PhD
- Gerard Gioia, PhD
- Christopher C. Giza, MD
- Wayne A. Gordon, PhD, ABPP-CN
- Kevin Guskiewicz, PhD, ATC
- Mark E. Halstead, MD
- Stanley A. Herring, MD
- Barbara Holshouser, PhD
- Madeline Matar Joseph, MD, FACEP, FAAP
- Angela Lumba-Brown, MD, FAAP
- Rosemarie Scolaro Moser, PhD, ABN, ABPP-RP
- Robert E. O'Connor, MD, MPH
- Theodore J. Spinks, MD, FAANS
- Stacy Suskauer, MD
- Michael Turner, MD
- Barbara Weissman, MD
- David W. Wright, MD, FACEP
- Keith Owen Yeates, PhD, ABPP

# Ad-Hoc Experts

- Katrina Altenhofen, MPH, Paramedic, CME, CCPSTI
- James M. Callahan, MD
- Meeryo C. Choe, MD
- Cindy W. Christian, MD
- Micky Collins, PhD
- John DeWitt, PT, DPT, SCS, ATC
- Ann-Christine Duhaime, MD
- Richard G. Ellenbogen, MD, FACS
- Theodore G. Ganiats, MD
- Andrew Gregory, MD, FAAP, FACSM
- Heather Keenan, PhD, MPH, MDCM
- Michael Kirkwood, PhD, ABPP-CN
- Karen McAvoy, PsyD
- Anne Mucha, PT, DPT, MS, NCS
- David Paulk, PA-C, EdD, DFAAPA
- Margot Putukian, MD, FACSM
- John Ragheb, MD, FACS, FAAP
- Patricia B. Raksin, MD
- Sally Schoessler, MSEd, BSN, RN
- H. Gerry Taylor, PhD
- Shari Wade, PhD



# Federal Representatives

Designated Federal Officer to the Workgroup: Kelly Sarmiento, MPH (Centers for Disease Control and Prevention)

- Elizabeth A. Edgerton, MD, MPH (Health Resources & Services Administration, Emergency Medical Services for Children)
- Jason Goldsmith, PhD (Consumer Product Safety Commission)
- Deborah Hirtz, MD (National Institutes of Health)
- James Kelly, MD (U.S. Department of Defense)
- A. Cate Miller, PhD (U.S. Department of Education)
- Therese A. West, DNP, APN, BC (U.S. Department of Defense)

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Angela Lumba-Brown, MD



Keith Yeates, PhD

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  - Michael Turner, MD, Question 1 Assignment Lead
  - Stacy Suskauer, MD, Question 2 Assignment Lead
  - Madeline Joseph, MD, Question 3 Assignment Lead
  - Christopher Giza, MD, and Catherine Broomand, PhD, ABPP-CN, Question 4 Assignment Leads
  - Keith Yeates, PhD, Question 5 Assignment Lead
  - Angela Lumba-Brown, MD, Question 6 Assignment Lead
- For their expertise as recommendation assignment leads:
  - Michael Turner, MD, Diagnosis Assignment Lead
  - Edward Benzel, MD, Prognosis Assignment Lead
  - Gerard A. Gioia, PhD, Management and Treatment Assignment Lead

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  - Linda Sabelhaus, MLS
  - Nicole Vetter
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**THANK YOU!**